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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/992,433	11/16/2001	Sikander Randhava	13909-00002	6093

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EXAMINER
TATE, CHRISTOPHER ROBIN

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/992,433	Randhava et al.
Examiner	**Art Unit**
Christopher Tate	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 9, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-23* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The supplemental amendment filed May 13, 2003 is acknowledged and has been entered. Claims 1-23 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 U.S.C. § 112

Claims 11 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 remains vague and indefinite because it is still not clear from the body of this Jepsen claim if the improved composition actually contains saw palmetto extract therein. The insertion of the term "improved" (line 1) does not obviate this rejection.

Claim Rejections - 35 U.S.C. § 102

Claims 1-3, 6-8, and 11-23 stand rejected under 35 U.S.C. 102(e) as being anticipated by Mann (US 6,231,866) for the reasons set forth in the previous Office action which are restated below.

Mann teaches a controlled release composition comprising saw palmetto extract (termed SAW-MAX) useful for treating BPH, including formulating the composition into a capsule (thus capsulation) which coats/shields the internal bioactive agent from stomach acid degradation so as to release a maximum concentration of bioactive agent to the intestines (see entire document including col 2, lines 3-61; col 5, lines 40-67; col 8, lines 38-49; col 9, line 14 - col 10, line 33). The controlled release composition taught by Mann would inherently initially release saw palmetto extract in the duodenum and before it enters the colon.

Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1-3, 6-8, 11, 18-23 stand rejected under 35 U.S.C. 102(e) as being anticipated by Wilding (US 2001/0008638) for the reasons set forth in the previous Office action which are restated below.

Wilding teaches a controlled release composition (including capsules) comprising saw palmetto extract that comprises two or more enteric coatings, whereby the controlled release formulation may be one of numerous prior art controlled release formulations (see, e.g., page 2, paragraphs 0016-23) including some which would inherently withstand stomach acid degradation and allow release of the saw palmetto extract into the duodenum before entering the colon.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 U.S.C. § 103

Claims 1-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding (US 2001/0008638) or Mann (US 6,231,866), in view of Locke (US 6,200,573) and Acharya (US 5,102,666) for the reasons set forth in the previous Office action which are restated below.

Wilding and Mann are relied upon for the reasons discussed *supra*. In addition, although Wilding does not expressly teach treating BPH via administering the controlled release formulation containing saw palmetto extract, Wilding discloses that the saw palmetto extract is an anti-estrogen ingredient which is useful for treating BPH by decreasing the conversion of testosterone to DHT (see, e.g., page 1, paragraphs 0007- 0008). Further, although Mann does not expressly teach encapsulating the SAW-MAX preparation within an enteric-type coating, Mann does disclose that the SAW-MAX controlled release formulation may optionally be encapsulated (see, e.g., col 10, lines 30-33). Neither of the primary references expressly teach the inclusion of a compound which minimizes (inhibits) smooth muscle contraction - such as peppermint.

Locke beneficially teaches treating BPH via oral administration of a composition (including a capsule) comprising saw palmetto extract and an alpha-adrenergic antagonist compound which inhibits (minimizes) prostatic smooth muscle contraction - i.e., relaxes the prostatic smooth muscle. Locke also beneficially teaches that the composition can be formulated into a once-a-day or even longer sustained release composition using conventional techniques well known in the art (see, e.g., abstract; col 2, lines 4-22; col 3, lines 25-44; col 5, lines 27-42; col 7, line 55 - col 8, line 3; col 9, lines 23-35; and claims).

Acharya beneficially teaches the inclusion of peppermint oil as a flavoring agent to controlled release pharmaceutical formulations including capsules (see, e.g., col 8, lines 6-16).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer one or more of the controlled-release saw palmetto extract-containing compositions taught by either of the primary references to a patient suffering from BPH based upon the beneficially teaching provided therein. It would also have been obvious to one of ordinary skill in the art to further include a compound which inhibits smooth muscle contraction therein based upon the beneficial teachings provided by Locke, and/or to include peppermint as a well known flavoring agent therein based upon the beneficial teachings provided by Acharya (please note that peppermint flavoring would intrinsically provide the functional effect instantly claimed). The adjustment of particular conventional working conditions (e.g., coating the SAW-MAX formulation of Mann with a conventional enteric coating or other controlled release-type coating; and/or determining a result-effective prior art controlled release formulation in which to incorporate the cited saw palmetto extract compositions so as to effectively release the saw palmetto extracts into the duodenum/small intestines - especially given that Wilding clearly indicates that various types of prior art controlled release formulation technologies can be used to accomplish this controlled-release feature) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jia (US 2002/0071869), in view of Mann (US 6,231,866), Wilding (US 2001/0008638), and Locke (US 6,200,573), and further in view of Acharya (US 5,102,666) for the reasons set forth in the previous Office action which are restated below.

The Mann and Wilding references are relied upon for the reasons discussed *supra*.

Jia teaches the incorporation of a biologically active agent such as saw palmetto extract within a bioadhesive preparation so as to protect and target the delivery of the bioactive agent to target cells. Jia also discloses that the bioadhesive composition can be formulated within time-release capsules (see, e.g., pages 1-2, paragraph 0007-0008 and 0018; page 4, paragraphs 0034-0035; and claims).

Locke beneficially teaches treating BPH via oral administration of a composition (including a capsule) comprising saw palmetto extract and an alpha-adrenergic antagonist compound which inhibits (minimizes) prostatic smooth muscle contraction- i.e., relaxes the prostatic smooth muscle. Locke also beneficially teaches that the composition can be formulated into a once-a-day or even longer sustained release composition using conventional techniques well known in the art (see, e.g., abstract; col 2, lines 4-22; col 3, lines 25-44; col 5, lines 27-42; col 7, line 55 - col 8, line 3; col 9, lines 23-35; and claims).

Acharya beneficially teaches the inclusion of peppermint oil as a flavoring agent to controlled release pharmaceutical formulations including capsules (see, e.g., col 8, lines 6-16).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate the bioadhesive saw palmetto extract preparation of Jia within a time-release/controlled-release formulation and to treat BPH using such a formulation based upon the beneficial teaching provided by Mann, Wilding, and Locke, with respect to time-release/controlled release saw palmetto extract formulations useful for treating BPH.

It would further have been obvious to one of ordinary skill in the art to further include a compound which inhibits smooth muscle contraction therein based upon the beneficial teachings provided by Locke, and/or to include peppermint as a well known flavoring agent therein based upon the beneficial teachings provided by Acharya (please note that peppermint flavoring would intrinsically provide the functional effect instantly claimed). The adjustment of particular conventional working conditions (e.g., coating the bioadhesive formulation taught by Jia with a

conventional enteric coating or other time-release/controlled release-type coating; and/or determining a result-effective prior art controlled release formulation in which to incorporate the cited saw palmetto extract compositions so as to effectively release the saw palmetto extracts into the duodenum/small intestines - especially given that Wilding clearly indicates that various types of prior art controlled release formulation technologies can be used to accomplish this controlled-release feature) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Applicants' arguments with respect to the art rejections above have been carefully considered but are not deemed to be persuasive of error in the rejections.

Applicants argue that Mann does not teach a saw palmetto extract as defined by the instant specification - i.e., "the extract of saw palmetto plant in the form of an oil, a water-soluble concentrate, or an alcohol-soluble concentrate" because the SAW-MAX product disclosed by Mann is produced by infusing saw palmetto oil into saw palmetto pomace (of plant parts). However, the infused saw palmetto oil taught by Mann properly reads upon the instantly disclosed/claimed saw palmetto extract since the SAW MAX disclosed by Mann is, in fact, composed of saw palmetto oil (which is extracted from saw palmetto) and the instant claims recite "...composition ... comprising saw palmetto extract" which is open language with respect

to permitting additional ingredients to be incorporated therein. Applicants further argue that Wilding does not teach saw palmetto extract without prohormone. However, it is reemphasized that the instant claims recite "...composition ... comprising saw palmetto extract" which is open language with respect to the incorporation of additional ingredients therein - i.e., the argued limitations are not commiserate with that of the claimed subject matter. Please note that while claims must be "given the broadest reasonable interpretation consistent with the specification", "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from `reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." In re Prater , 162 USPQ 541, 550 - 51 (CCPA 1969).

Applicants further argue that Locke does not teach an antispasmodic drug but instead teaches alpha-adrenergic agonists. However, the claims recite "a compound that minimizes smooth muscle contractions", not an antispasmodic drug as argued. Further, as discussed above, Locke et al. discloses that such alpha-adrenergic antagonist inhibit (minimize) prostatic smooth muscle contraction and, thus, would intrinsically relax prostatic smooth muscle. Applicants also argue that Acharya does not teach or suggest that their controlled release composition can be used with saw palmetto extract and, thus, there is no motivation to combine Acharya with the above cited references. However, as discussed above, Acharya was cited to show that peppermint oil is often beneficially used as a flavoring agent within controlled release

formulations including capsules and that such conventionally employed peppermint oil flavoring would intrinsically provide the functional effect instantly claimed.

With respect to the U.S.C. 103 rejections above, Applicants have argued and discussed references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicants' claimed invention fails to patentably distinguish over the state of the art represented by the references.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.

Christopher R. Tate
Primary Examiner, Group 1654